DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FOCUS DIAGNOSTICS, INC.
SHARON YOUNG
SENIOR REGULATORY AFFAIRS SPECIALIST
11331 VALLEY VIEW ST
CYPRESS CA 90630

March 18, 2015

Re: K143651
Trade/Device Name: Simplexa™ Group A Strep Direct, Simplexa™ Group A Strep Positive Control Pack
Regulation Number: 21 CFR 866.2680
Regulation Name: Streptococcus spp. nucleic acid-based assay
Regulatory Class: II
Product Code: PGX, OOI
Dated: December 22, 2014
Received: December 23, 2014

Dear Ms. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143651

Device Name
Simplexa™ Group A Strep Direct and Simplexa™ Group A Strep Positive Control Pack

Indications for Use *(Describe)*

Simplexa™ Group A Strep Direct

The Focus Diagnostics Simplexa™ Group A Strep Direct assay is intended for use on the 3M Integrated Cycler for the in vitro qualitative detection of Group A Streptococcus (GAS) from throat swabs collected from human patients with signs and symptoms of pharyngitis, such as sore throat. This test is intended for use as an aid in the diagnosis of GAS infection. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use.

Simplexa™ Group A Strep Positive Control Pack

Focus Diagnostics' Simplexa™ Group A Strep Positive Control Pack is intended to be used as a control with Simplexa™ Group A Strep Direct. This control is not intended for use with other assays or systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Applicant	Focus Diagnostics, Inc. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Sharon Young tel 562.240.6680 fax 562.240.6529 syoung@focusdx.com
Summary Date	March 17, 2015
Proprietary Name	Simplexa™ Group A Strep Direct Simplexa™ Group A Strep Positive Control Pack
Generic Name	Group A *Streptococcus* nucleic acid
Classification **Regulation** **Product Code**	Class II 21 CFR 866.2680 PGX
Predicate Device	Lyra™ Direct Strep Assay k133883,

Intended Use

Simplexa™ Group A Strep Direct

The Focus Diagnostics Simplexa™ Group A Strep Direct assay is intended for use on the 3M Integrated Cycler for the *in vitro* qualitative detection of Group A Streptococcus (GAS) from throat swabs collected from human patients with signs and symptoms of pharyngitis, such as sore throat. This test is intended for use as an aid in the diagnosis of GAS infection. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use.

Simplexa™ Group A Strep Positive Control Pack

Focus Diagnostics' Simplexa™ Group A Strep Positive Control Pack is intended to be used as a control with Simplexa™ Group A Strep Direct. This control is not intended for use with other assays or systems.

Device Description

The Simplexa™ Group A Strep Direct assay system is a real-time PCR system that enables the direct amplification and qualitative detection of Group A Strep bacterial DNA from throat swabs that have not undergone a nucleic acid extraction. The system consists of the Simplexa™ Group A Strep Direct assay, the 3M Integrated Cycler (with Integrated Cycler Studio Software), the Direct Amplification Disc (DAD) and associated accessories.

In the Simplexa™ Group A Strep Direct assay, bi-functional fluorescent probe-primers are used together with corresponding reverse primers to amplify Group A Strep bacterial DNA and the Internal Control (DNA IC). The assay targets a conserved region of Group A Strep (pyrogenic exotoxin B gene) to identify this bacteria in the specimen. The DNA IC is used to detect PCR failure and/or inhibition.

Predicate Device Information

Item	Device	Predicate
Name	**Simplexa™ Group A Strep Direct**	**Lyra™ Direct Strep Assay K133883**
Intended Use	Simplexa™ Group A Strep Direct The Focus Diagnostics Simplexa™ Group A Strep Direct assay is intended for use on the 3M Integrated Cycler for the in vitro qualitative detection of Group A Streptococcus (GAS) from throat swabs collected from human patients with signs and symptoms of pharyngitis, such as sore throat. This test is intended for use as an aid in the diagnosis of GAS infection. This test is intended for use as an aid in the diagnosis of GAS infection. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use. Simplexa™ Group A Strep Positive Control Pack Focus Diagnostics' Simplexa™ Group A Strep Positive Control Pack is intended to be used as a control with Simplexa™ Group A Strep Direct. This control is not intended for use with other assays or systems.	The Lyra Direct Strep Assay is a Real-Time PCR in vitro diagnostic test for the qualitative detection and differentiation of Group A β-hemolytic Streptococcus (Streptococcus pyogenes) and pyogenic Group C and G β-hemolytic Streptococcus nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as a sore throat. The assay does not differentiate between pyogenic Groups C and G β-hemolytic Streptococcus. All negative test results should be confirmed by bacterial culture, because negative results do not preclude Group A, C or G Strep infection and should not be used as the sole basis for treatment. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use.
Assay Targets	Group A *streptococcus* – *Streptococcus pyogenes*	Group A *streptococcus* – *Streptococcus pyogenes*
Assay Type	Qualitative	Qualitative
Sample Types	Throat swab	Throat Swab
Extraction Methods	Self-contained and automated	Manual
Assay Methodology	PCR-based system for detecting the presence / absence of bacterial DNA in clinical specimens	PCR-based system for detecting the presence / absence of bacterial DNA in clinical specimens
Detection Techniques	Singleplex assay using different reporter dyes for each target.	Triplex assay using different reporter dyes for each target.
Group A Strep Bacterial Target	Well conserved region of the exotoxin B gene (speB)	Group A – 99bp product in the putative competence (comX1.1) gene Groups C/G – 188bp product in the tagatose-6-phosphate kinase (lacC) gene
Instrumentation	3M Integrated Cycler	ABI 7500 Fast DX Thermocycler

Item	Device	Predicate
Name	Simplexa™ Group A Strep Direct	Lyra™ Direct Strep Assay K133883
Performance Characteristics	Sensitivity: 97.4% (152/156) (95% CI: 93.6% to 99.0%) Specificity: 95.2% (1139/1196) (95% CI: 93.9% to 96.3%)	GAS Sensitivity: 96.5% (95% CI: 91.3% - 98.6%) GAS Specificity: 98.0% (95% CI: 97.0% - 98.6%) Pyo GCS/GGS Sensitivity: 95.7% (95% CI: 88.1% - 98.5%) Pyo GCS/GGS Specificity: 98.3% (95% CI: 97.4% - 98.9%)

REPRODUCIBILITY

Three (3) investigative sites assessed the device's inter-site, inter-day and inter/intra-assay reproducibility. Each of the laboratories tested a panel of six (6) members that included contrived samples at low positive, (approximately 1 X LoD) and moderately positive sample (approximately 3 X LoD) for M1 and M3 serotypes of Group A Streptococcus, a positive and negative control were also included in the panel. The assays were performed in triplicate (3) on five (5) different days. Each site had two (2) operators who each assayed the sample panel once (1) per day, for a total of two (2) sets of data per day. Combined results for all sites are presented in the tables below.

Sample Panel Member	Testing Site 1			Testing Site 2			Testing Site 3			Overall	
	% Agreement with Expected Results	Avg. Ct	% CV	% Agreement with Expected Results	Avg. Ct	% CV	% Agreement with Expected Results	Avg. Ct	% CV	Total %	95% CI
Negative	100.0% (30/30)	NA	NA	96.7% (29/30)	41.9	NA	100.0% (30/30)	NA	NA	98.9% (89/90)	94.0 to 99.8%
Positive Control (PC)	100.0% (30/30)	29.5	1.4	100.0% (30/30)	29.5	3	100.0% (30/30)	30	1.2	100.0% (90/90)	95.9 to 100.0%
Group A Strep M1 Serotype Low Positive	100.0% (30/30)	38.6	4.4	83.3% (25/30)	39.4	5.6	96.7% (29/30)	38	3.5	93.3% (84/90)	86.2 to 96.9%
Group A Strep M1 Serotype Moderate Positive	100.0% (30/30)	35.9	2.6	93.3% (28/30)	36.3	4.8	100.0% (30/30)	36	1.8	97.8% (88/90)	92.3 to 99.4%
Group A Strep M3 Serotype Low Positive	96.7% (29/30)	38.5	2.9	90.0% (27/30)	39.2	4.8	96.7% (29/30)	39	4.5	94.4% (85/90)	87.6 to 97.6%
Group A Strep M3 Serotype Moderate Positive	100.0% (30/30)	36.3	2.6	90.0% (27/30)	36.7	3.2	100.0% (30/30)	37	2.7	96.7% (87/90)	90.7 to 98.9%
All	99.4% (179/180)			92.2% (166/180)			98.9% (178/180)			96.9% (523/540)	95.0 to 98.0%

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION

The Limit of Detection (LoD) was determined for the Simplexa™ Group A Strep Direct by performing a dilution series. The LoD samples used for the study were contrived using two (2) serotypes of Group A Streptococcus; M1 and M3 that were verified (re-grown and re-titered) bacterial stock. For each serotype, eight (8) different concentrations were spiked in simulated matrix from the verified bacterial stock material and confirmed using thirty two (32) replicates. The Limit of Detection (LoD) was determined to be the following;

Simplexa™ Group A Strep Direct – Limit of Detection	
Group A Strep Serotype	**Concentration (cfu/mL)**
M1	682
M3	2350

ANALYTICAL REACTIVITY / CROSS REACTIVITY

Analytical Reactivity

Analytical Reactivity was assessed for the ability of Simplexa™ Group A Strep Direct to detect sixty (60) Group A Streptococcus strains not present in the LoD study. Analytical Reactivity was observed in testing of twenty one (21) strains. All were detected as positive for Group A Strep at or below 5000 cfu/mL. Analytical Reactivity was tested using in silico NCBI BLAST sequence analysis methods for thirty nine (39) GAS strains distinct from the wet tested strains.

Streptococcus pyogenes **Serotype**	**Concentration (cfu/mL)**	**Simplexa™ Group A Strep Direct Qualitative Result % Detection**
M2	1.50×10^3	100% (3/3)
M4	1.50×10^3	100% (3/3)
M5	1.50×10^3	100% (3/3)
M6	1.50×10^3	100% (3/3)
M9	3.00×10^3	100% (3/3)
M12	1.50×10^3	100% (3/3)
M13	1.50×10^3	100% (3/3)
M14	1.50×10^3	100% (3/3)
M18	5.00×10^3	100% (3/3)
M22	1.50×10^3	100% (3/3)
M27	3.00×10^3	100% (3/3)
M28	1.50×10^3	100% (3/3)
M29	1.50×10^3	100% (3/3)
M49	1.50×10^3	100% (3/3)
M73	3.00×10^3	100% (3/3)
M75	3.00×10^3	100% (3/3)
M77	3.00×10^3	100% (3/3)
M78	1.50×10^3	100% (3/3)

Streptococcus pyogenes Serotype	Concentration (cfu/mL)	Simplexa™ Group A Strep Direct Qualitative Result % Detection
M82	1.50×10^3	100% (3/3)
M87	1.50×10^3	100% (3/3)
M89	3.00×10^3	100% (3/3)

Cross Reactivity (Analytical Specificity)

Analytical reactivity was evaluated for the Simplexa™ Group A Strep Direct by testing the ability to exclusively identify Group A Streptococcus with no cross reactivity to organisms that are closely related, or cause similar clinical symptoms, or present as normal flora in the pharynx. Negative specimens were spiked with potentially cross-reactive organisms at known concentrations. Spiked specimens were examined for reactivity with the Group A Strep Direct. Sixty four (64) organisms were tested. *Bacteroides ovalis* and *Tremella fuciformis* were not available for testing therefore data from In-Silico NCBI BLAST sequence analysis was performed. No cross reactivity was found

Cross Reactant	Tested Concentration	Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)
Baseline1	Not Applicable	0.0% (0/5)
Baseline2	Not Applicable	0.0% (0/5)
Adenovirus 1	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Adenovirus 7A	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Arcanobacterium haemolyticum	1.00×10^6 $TCID_{50}$/mL	0.0% (0/3)
Bacillus cereus	1.00×10^6 cfu/mL	0.0% (0/3)
Bacteroides ovatus	1.00×10^6 cfu/mL	0.0% (0/3)
Bordetella pertussis	1.00×10^6 cfu/mL	0.0% (0/3)
Burkholderia cepacia	1.00×10^6 cfu/mL	0.0% (0/3)
Campylobacter rectus	1.00×10^6 cfu/mL	0.0% (0/3)
Candida albicans	1.00×10^6 cfu/mL	0.0% (0/3)
Chlamydia pneumoniae	1.00×10^6 cfu/mL	0.0% (0/3)
Coronavirus 229E	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Corynebacterium diphtheriae	1.00×10^6 $TCID_{50}$/mL	0.0% (0/3)
Cytomegalovirus (CMV)	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Enterococcus faecalis vanB	1.00×10^6 cfu/mL	0.0% (0/3)
Enterovirus 71	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Epstein-Barr virus (B95-8)	1.00×10^5 copies/mL	0.0% (0/3)
Escherichia coli	1.00×10^6 cfu/mL	0.0% (0/3)
Fusobacterium necrophorum	1.00×10^6 cfu/mL	0.0% (0/3)
Haemophilus influenzae	1.00×10^6 cfu/mL	0.0% (0/3)

Cross Reactant	Tested Concentration	Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)
HSV-1 McIntyre	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
HSV-2 G	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Influenza A/Hong Kong/8/68 H3N2	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Influenza B/Panama/45/90	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Klebsiella pneumoniae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Lactobacillus acidophilus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Legionella pneumophila	1.00 X 10^6 cfu/mL	0.0% (0/3)
Metapneumovirus-9	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Moraxella catarrhalis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Mycoplasma pneumoniae	1.00 X 10^6 CCU/ml	0.0% (0/3)
Neisseria gonorrhoeae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Neisseria meningitidis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Parainfluenza 1	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Parainfluenza 2	1.00 X 105 $TCID_{50}$/mL	0.0% (0/3)
Parainfluenza 3	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Peptostreptococcus micros	1.00 X 10^6 cfu/mL	0.0% (0/6)
Pseudomonas aeruginosa	1.00 X 106 cfu/mL	0.0% (0/3)
Rhinovirus 1A	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
RSV-B 9320	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Staphylococcus aureus (MRSA), ATCC 43300	1.00 X 10^6 cfu/mL	0.0% (0/3)
Staphylococcus epidermidis (MRSE), ATCC 29887	1.00 X 10^6 cfu/mL	0.0% (0/3)
Stenotrophomonas maltophilia	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus agalactiae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus anginosus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus canis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus constellatus subsp. constellatus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus cristatus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus dysgalactiae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus equi subsp. zooepidemicus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus equinus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus gallolyticus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus gordonii	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus intermedius	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus mitis	1.00 X 10^6 cfu/mL	0.0% (0/3)

Cross Reactant	Tested Concentration	Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)
Streptococcus mutans	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus oralis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus parasanguinis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus pneumoniae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus salivarius	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus sanguinis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus sobrinus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus uberis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus vestibularis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Treponema denticola	1.00 X 10^6 spirochetes/mL	0.0% (0/3)
Veillonella parvula	1.00 X 10^6 cfu/mL	0.0% (0/3)

INTERFERENCE

The performance of Simplexa™ Group A Strep Direct was evaluated with potentially interfering substances that may be present in pharynx. The potentially interfering substances were evaluated in a contrived sample that contained Group A Streptococcus at low positive concentrations (approximately 1 X LoD) and moderate positive concentrations (approximately 3 X LoD) of Group A Streptococcus serotypes M1 and M3. There was no evidence of interference caused by the substances at the concentrations tested.

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Baseline	Not Applicable	Not Applicable	M1	100.0%(5/5)
Baseline	Not Applicable	Not Applicable	M3	100.0%(5/5)
Afrin nasal Spray	Oxymetazoline Hydrochloride	15% v/v	M1	100.0%(3/3)
Afrin nasal Spray	Oxymetazoline Hydrochloride	15% v/v	M3	100.0%(3/3)
Antibiotic	Amoxicillin	0.5 mg/mL	M1	100.0%(3/3)
Antibiotic	Amoxicillin	0.5 mg/mL	M3	100.0%(3/3)
Antibiotic	Cephalexin	0.04 mg/mL	M1	100.0%(3/3)
Antibiotic	Cephalexin	0.04 mg/mL	M3	100.0%(3/3)
Antibiotic	Clindamycin	0.06 mg/mL	M1	100.0%(5/5)
Antibiotic	Clindamycin	0.06 mg/mL	M3	100.0%(3/3)
Antibiotic	Erythromycin	1 mg/mL	M1	100.0%(3/3)
Antibiotic	Erythromycin	1 mg/mL	M3	100.0%(3/3)
Antibiotic	Penicillin	1200 U/mL	M1	100.0%(3/3)
Antibiotic	Penicillin	1200 U/mL	M3	100.0%(3/3)
Aspirin	Aspirin	0.62 mg/mL	M1	100.0%(3/3)

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Aspirin	Aspirin	0.62 mg/mL	M3	100.0%(3/3)
Benadryl	Diphenhydramine HCl	10 µL/swab	M1	100.0%(3/3)
Benadryl	Diphenhydramine HCl	10 µL/swab	M3	100.0%(3/3)
Blood	Blood	10% v/v	M1	100.0%(3/3)
Blood	Blood	10% v/v	M3	100.0%(3/3)
Chloraseptic Sore Throat Spray	Phenol	10% v/v	M1	100.0%(3/3)
Chloraseptic Sore Throat Spray	Phenol	10% v/v	M3	100.0%(3/3)
Contac Cold + Flu tablet	Acetaminophen Chlorpheniramine Maleate Phenylephrine HCl	16.2 mg/mL 0.06 mg/mL 0.16 mg/mL	M1	100.0%(3/3)
Contac Cold + Flu tablet	Acetaminophen Chlorpheniramine Maleate Phenylephrine HCl	16.2 mg/mL 0.06 mg/mL 0.16 mg/mL	M3	100.0%(3/3)
Corticosterone	Corticosterone	4 mg/swab	M1	100.0%(3/3)
Corticosterone	Corticosterone	4 mg/swab	M3	100.0%(3/3)
Crest Complete Toothpaste	Sodium Fluoride	0.1 mg/mL	M1	100.0%(3/3)
Crest Complete Toothpaste	Sodium Fluoride	0.1 mg/mL	M3	100.0%(3/3)
Finafta Oral Anesthetic / Analgesics	Ethyl Alcohol Salicylic Acid Benzocaine	1/10X dilution	M1	100.0%(3/3)
Finafta Oral Anesthetic / Analgesics	Ethyl Alcohol Salicylic Acid Benzocaine	1/10X dilution	M3	100.0%(3/3)
Listerine	Eucalyptol Menthol Methyl Salicylate Thymol	10 µL/swab	M1	100.0%(3/3)
Listerine	Eucalyptol Menthol Methyl Salicylate Thymol	10 µL/swab	M3	100.0%(3/3)
Mucin	Purified Mucin Protein	60 µg/mL	M1	100.0%(3/3)
Mucin	Purified Mucin Protein	60 µg/mL	M3	100.0%(3/3)
Neo-Synephrine	Phenylephrine HCl	15% v/v	M1	100.0%(3/3)
Neo-Synephrine	Phenylephrine HCl	15% v/v	M3	100.0%(3/3)

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Nyquil	Dextromethorphan Hydrobromide Doxylamine Succinate	1/200 X dilution	M1	100.0%(3/3)
Nyquil	Dextromethorphan Hydrobromide Doxylamine Succinate	1/200 X dilution	M3	100.0%(3/3)
Pain Medication	NSAID	0.1 mg/mL	M1	100.0%(3/3)
Pain Medication	NSAID	0.1 mg/mL	M3	100.0%(3/3)
Pain Medication	Tylenol	1 mg/mL	M1	100.0%(3/3)
Pain Medication	Tylenol	1 mg/mL	M3	100.0%(3/3)
Robitussin Cough / Chest Congestion Cough Syrup	Dextromethorphan HBr Guaifenesin	2.0 mg/mL	M1	100.0%(3/3)
Robitussin Cough / Chest Congestion Cough Syrup	Dextromethorphan HBr Guaifenesin	2.0 mg/mL	M3	100.0%(3/3)
Saline Nasal Spray	Sodium Chloride with Preservatives	15% v/v	M1	100.0%(3/3)
Saline Nasal Spray	Sodium Chloride with Preservatives	15% v/v	M3	100.0%(3/3)
Saliva	Water, Electrolytes, Mucus, Etc.	50 µL/swab	M1	100.0%(3/3)
Saliva	Water, Electrolytes, Mucus, Etc.	50 µL/swab	M3	100.0%(3/3)
Scope	Glycerin Sodium Saccharin Sodium Benzoate Cetylpyridinum Chloride Benzoic Acid Blue 1 Yellow 5	10 µL/swab	M1	100.0%(3/3)
Scope	Glycerin Sodium Saccharin Sodium Benzoate Cetylpyridinum Chloride Benzoic Acid Blue 1 Yellow 5	10 µL/swab	M3	100.0%(3/3)
Sore Throat Lozenge	Menthol	1.7 mg/mL	M1	100.0%(3/3)
Sore Throat Lozenge	Menthol	1.7 mg/mL	M3	100.0%(3/3)
Sore Throat Lozenge	Pectin	0.34 mg/mL	M1	100.0%(3/3)
Sore Throat Lozenge	Pectin	0.34 mg/mL	M3	100.0%(3/3)

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Sore Throat Lozenge	Zinc Gluconate Glycine	0.1 mg/mL	M1	100.0%(3/3)
Sore Throat Lozenge	Zinc Gluconate Glycine	0.1 mg/mL	M3	100.0%(3/3)
Thymol	Thymol	400 mg/swab	M1	100.0%(3/3)
Thymol	Thymol	400 mg/swab	M3	100.0%(3/3)
Zicam Oral Mist	Zincum Aceticum Zincum Gluonicum	0.625% v/v	M1	100.0%(3/3)
Zicam Oral Mist	Zincum Aceticum Zincum Gluonicum	0.625% v/v	M3	100.0%(3/3)

CLINICAL PROSPECTIVE STUDY

One thousand three hundred and ninety seven (1397) samples that were prospectively collected from four (4) geographically diverse sites between May 6, 2014 and October 28, 2014 from patients with signs and symptoms of Group A Strep infections of the pharynx. One thousand three hundred and fifty two (1352) samples were evaluable on Simplexa™ Group A Strep Direct and the comparator culture method. Samples were tested on Simplexa™ Group A Strep Direct at the collection sites and comparator culture method was performed at one (1) central laboratory. The invalid rate of the clinical prospective study using Simplexa™ Group A Strep Direct was 0.57% (eight out of one thousand three hundred and ninety six 8/1396 samples). Discrepant analysis was performed using a validated bidirectional sequencing assay.

Clinical Prospective Study: (Overall)			
Simplexa™ Group A Strep Direct Result	**Culture Method**		
	Detected	**Not Detected**	**Total**
Detected	152	57[a]	209
Not Detected	4[b]	1139	1143
Total	156	1196	1352
%Sensitivity	97.4%(152/156) 95% CI: 93.6% to 99.0%	%Specificity	95.2%(1139/1196) 95% CI: 93.9% to 96.3%
% Positive Predictive Value (PPV)	72.7%(152/209) 95% CI: 66.3% to 78.3%	%Negative Predictive Value (NPV)	99.7%(1139/1143) 95% CI: 99.1% to 99.9%

[a]46/57 discrepant samples were Group A Strep Positive, 9/57 were "Group A Strep Negative and 2/57 were Indeterminate when tested using a validated bidirectional sequencing assay.
[b]2/ 4 discrepant samples were Group A Strep Positive and 2/4 were Group A Strep Negative when tested using a validated bidirectional sequencing assay.

CONCLUSION

The conclusions drawn from the nonclinical and clinical tests demonstrate the device is as safe and effective as the legally marketed device identified above.